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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/180,657 11/12/98 MEIKLE

P 2325-1-002

EXAMINER

HM12/0419

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ART UNIT	PAPER NUMBER

1644

DATE MAILED:

04/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/180,657

Applicant
Miekle et al.

Examiner
Patrick Nolan

Group Art Unit
1644



☒ Responsive to communication(s) filed on Feb 2, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 52, 53, 55-74, 93, and 94 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 52, 53, 55-74, 93, and 94 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

1. Claims 52-53, 55-74 and 93-94 are pending.
2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 52-53, 55-74 and 93-94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting an increase in LAMP-1 expression, 4-sulphatase activity, acid phosphatase activity, β -hexosaminidase activity and α -mannosidase activity and correlating said increase to an LSD, does not reasonably provide enablement for the detection of an LSD and the increase or decrease of LAMP-2, LIMP-2, Mannose-6-Phosphate receptors or a change in the activity of α -L-iduronidase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

Applicants specification clearly teaches it is unpredictable whether or not a LSD marker will be increased and whether or not said increase correlates to the detection of an LSD. Table 3 clearly teaches that α -L-iduronidase activity was not changed in Pompe disease, MPS-II disease, MPS-VI disease or in the sucrosome LSD model. In addition Figure 5, clearly teach that LAMP-2 levels were significantly different from controls in 4 types of LSD affected individuals. Lastly, since the Applicant's own working examples cast some unpredictability on the ability of some of the markers to correlate to all LSD diseases, those markers not even tested, LIMP-II and Mannose-6-Phosphate receptors would clearly be unpredictable in their ability to correlate an LSD disease with said marker. Since Applicant's own working examples clearly teach it is unpredictable whether or not an LSD marker will be increased or decreased and detect an LSD it would require an undue amount of experimentation to practice the full breadth Applicant's claimed invention.

4. Claims 52-53, 55-74 and 93-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is claimed by the recitation of LAMP-I, LAMP-II or LIMP-II. Correction by the insertion of the art

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recognized full length name the first time the abbreviation is used will overcome this rejection.

In addition it is unclear what is meant by the term immunointeractive molecule in claim 66. Applicant has support for an antibody molecule or an antigen binding fragment thereof. Correction for claim definiteness is requested.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm.

6. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan

Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
April 18, 2001